Remarks/Arguments

Prior to the current amendments, claims 1, 3-5, 7-20, 22-27, 29-42, and 44-46 were pending in this application. Claims 1, 4, 5, 7-20, 22-34 and 46 were rejected, claims 3, 35-42, and 44-45 were objected to. As a result of the present amendment, claims 1, 7, 41, 42, and 44 have been amended, claims 3, 18-20, 22-27, 29-35, 40, and 46 were canceled. The claim amendments are fully supported by the specification as originally filed. Thus, for example, the amendments in claims 1 and 2 are supported at least at page 7, lines 5-21 and by the examples. Support for the amendments in claims 39, 41, and 42 is at least at page 20, lines 11-16. The amendments do not add new matter.

All amendments are made without prejudice and without acquiescing to any of the rejections, or the reasoning underlying any of the rejections. Applicants specifically reserve the right to pursue any canceled subject matter in one or more continuing applications.

Claim Rejections - 35 U.S.C. § 112

New Matter

(1) Claims 39-42 were rejected under 35 U.S.C. 112, first paragraph as allegedly failing to comply with the written description requirement. In particular, the recitation of "trastuzumab" in these claims was considered new matter. Without acquiescing in this rejection, claim 40 has been canceled, and claims 39, 41 and 42 have been amended to recited huMAbD5-8 (rhuMAb HER2). Specific support for this amendment is, for example, at page 20, lines 11-16. Accordingly, the new matter rejection should be withdrawn.

(2) Claims 1, 3-5, 7-20, 22-42, and 44-46 were rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite.

In particular, in claim 1, step (c), line 3, the phrase "with a labeled secondary antibody recognizing said analyte" was found "vague and indefinite." In the Examiner's view, it was "not clear whether this labeled secondary antibody binds only the portion of 'analyte' or both 'analyte' and the complex of the second antibody and the bound analyte." Applicants respectfully disagree. Claim 1, as currently amended, recites that the secondary antibody is used to determine the total amount of free anti-HER2 antibody and the anti-HER2 antibody bound to

HER2 ECD, and that this goal is achieved by choosing a secondary antibody that recognizes an epitope which is different from both the epitope recognized by the first antibody (recognizing free anti-HER2 antibody) and is also from the epitope recognized by HER2 ECD. This language makes it clear that the secondary antibody binds both free and complexed anti-HER2 antibody, which is why it can detect the total amount of frew anti-HER2 antibody and the anti-HER2 antibody bound to HER2 ECD.

Claims 39, and 41-42 were found indefinite in their recitation of a trade name. Since the claims have been amended to recite the designation of the referenced antibody, which is clearly identified in the specification, this rejection is believed to be moot.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 3-5, 7-20, 22-34, and 46 were rejected as allegedly obvious over Parsons et al. (US 5,518,887) in view of Nishimura et al. (US 4,803,154).

Parson et al. was cited for teaching an immunoassay for simultaneously measuring different analytes in a test sample, including a dual antibody format. Nishimura et al. was cited for teaching ELISA immunoassay by either using enzyme-labeled antibody to increase detection sensitivity.

Claims 3, 18-20, 22-34, and 46 have been canceled. The rejection of the remaining claims is respectfully traversed. On page 6 of the Office Action, under the heading "Allowable Subject Matter," the Examiner acknowledged that "no prior art teaches or fairly suggests providing a solid surface dual coated with an anti-HER2 first antibody and an anti-HER2 ECD second antibody to determine the amount of total HER2 analyte in a sample by comparing a standard curve generated with various purified analyte (sic)." This statement is in correct in that in a particular embodiment of the invention the first antibody is not an anti-HER2 antibody but an antibody binding to an anti-HER2 antibody, and the analyte is not HER2, rather an anti-HER2 antibody. Nonetheless, the Examiner's intention has apparently been to acknowledge the allowability of claims directed to the detection of the total amount of an anti-HER2 antibody in the presence of HER2 ECD, by using a standard curve. Since the claims are now directed to this embodiment, the rejection under 35 USC 103(a) should be withdrawn.

In conclusion, all claims pending in this application are believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Although no fees are believed to be due at this time, please charge any fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (**Attorney Docket No.: 39766-0066A**). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully Submitted,

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